NASA Procedural Requirements

NPR 7100.1
Effective Date: March 28, 2003
Expiration Date: June 07, 2013

COMPLIANCE IS MANDATORY

Printable Format (PDF)

Request Notification of Change (NASA Only)

Subject: Protection of Human Research Subjects (Revalidated 7/7/08)

Responsible Office: Office of the Chief Health & Medical Officer

| TOC | ChangeHistory | Preface | Chp1 | Chp2 | Chp3 | Chp4 | Chp5 | Chp6 | Chp7 | Chp8 | Chp9 | Chp10 | Chp11 | Chp12 | Chp13 | Chp14 | Chp15 | Chp16 | Chp17 | AppdxA | AppdxB | AppdxC | ALL |

CHAPTER 7. Informed Consent

7.1 Required Informed Consent

Except as provided in section 7.6 below, no PI may involve a human subject in research covered by this NPR unless the PI has obtained the informed consent of the subject or the subject's legally authorized representative. Such consent shall be sought only under circumstances that provide the prospective subject, or the subject's representative, with sufficient latitude and opportunity to decide whether or not to participate, while minimizing the possibility of coercion or undue influence. All information that is provided shall be in language understandable to the subject or the representative. No informed consent may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or which releases, or appears to release the PI, the sponsor, the institution, or its agents from liability for negligence.

7.2 Elements of Informed Consent

The following basic elements of informed consent information shall be provided to each subject in nontechnical, easily understood language:

7.2.1 A statement that explains that the study involves research. An explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

7.2.2 A description of foreseeable risks or discomforts to the subject.

7.2.3 A description of any benefits to the subject, or to others which may reasonably be expected from the research, or a statement that the research is of no benefit to the subject.

7.2.4 A disclosure of appropriate alternative procedures or courses of action or treatment that could be advantageous to the subject.

7.2.5 A statement describing the extent to which confidentiality of records identifying the subjects shall be maintained. (Special attention should be given to explaining the problem of maintaining confidentiality with electronically stored databases.)

7.2.6 For research involving more than minimal risk, an explanation as to whether any compensation and medical assistance are available if injury or illness occurs and, if so, of the specifics relating thereto and any other relevant information.

7.2.7 Identification of contacts for answers to pertinent questions concerning specifics of the research and the research subject's rights. The contact in the event of a research-related injury or illness to the subject should also be

identified.

7.2.8 Except as provided in sections 7.4.2 and 7.4.4 below, a statement that participation is voluntary, and that subjects have the right to refuse to participate and to discontinue participation in the research at any time and that they may do so without penalty or loss of benefits to which they would be otherwise entitled. If the subject, in fact, cannot withdraw at any given time (because it would be unwise, dangerous, or impossible), the circumstances must be explained to the subject in writing as part of the informed consent document.

7.2.9 Subjects concerned about protocol violations may request a meeting with the relevant IRB.

7.3 Subject Withdrawal From Nonspace-Based Research

7.3.1 Consideration for withdrawal from nonspace-based research is predicated upon the following:

7.3.2 Research subjects may withdraw from participation at any time without penalty or loss of benefits to which they are otherwise entitled.

7.3.3 In the event that a subject withdraws from nonspace flight research involving human subjects, NASA reserves the right to replace that individual with another test subject.

7.4 Subject Withdrawal From Space-Based Research

Consideration for withdrawal from space-based research includes the following:

7.4.1 Research subjects may withdraw from participation at any time without penalty or loss of benefits to which they are otherwise entitled.

7.4.2 In the event that the research subject is a crewmember,

7.4.2.1 The IRB-approved life science experiment is part of the central or core function of the mission,

7.4.2.2 The crewmember was clearly and completely informed of the experiment prior to assignment to the mission,

7.4.2.3 The crewmember formally consented to participate in the experiment,

7.4.2.4 No substantial change has occurred in the protocol since the crewmember's consent; and

7.4.2.5 No new interim scientific information has surfaced indicating that the initial protocol presents a more than minimal increase in health or medical safety risk and no new, safer techniques have become available; then

7.4.2.6 Withdrawal from research may result in removal of that individual from that mission. This action shall be based on the determination that it is in the best interest of the Government and to ensure mission success.

7.4.3 The determination of whether all conditions in section 7.4.2 have been met shall rest with the IRB that approved the initial protocol. In the case of NASA or international astronauts, or payload specialists, a review shall be conducted by the ANO to validate the findings of the IRB under section 7.4.2 and formulate a recommendation. Approval of the recommendation and final disposition shall rest with the AA for Space Operations Mission Directorate in consultation with the mission-sponsoring organization.

7.4.4 When a crewmember has withdrawn and all conditions in section 7.4.2 have been met, such withdrawal shall not influence career opportunities; however, it could be used in the decision process regarding assignments to a future mission in which similar life science experiments are central or core to the mission.

7.5 Supplementary Elements of Informed Consent

Additional elements of informed consent may include, when appropriate, one or more of the following elements of information:

7.5.1 A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant), which are currently unforeseeable.

7.5.2 Anticipated circumstances under which the subject's participation may be terminated by the PI without regard to the subject's consent.

7.5.3 Any additional monetary costs to the subject that may result from participation in the research.

7.5.4 The consequences of a subject's decision to withdraw from the research and prescribed procedures for an orderly termination of participation by the subject.

7.5.5 A statement that the subject shall be informed of significant new findings developed during the course of the research, including adverse reactions of other subjects participating in this research, which may affect the subject's willingness to continue participation.

7.5.6 The approximate number of subjects in the study.

7.5.7 Any collective impact of multiple protocols, if applicable.

7.5.8 PI disclosure of financial interest in the research study, to include the benefits the PI will derive from the study, or drugs or devices being developed through the study.

7.6 Waiver of Consent Elements

An IRB may approve a consent procedure that either does not include or otherwise alters some or all of the elements of informed consent set forth in this NPR; or the IRB may waive the requirements to obtain informed consent, provided that the IRB finds and documents each of the following:

7.6.1 The research involves no more than minimal risk to the subjects.

7.6.2 The waiver or alteration shall not adversely affect the rights and welfare of the subjects.

7.6.3 The research could not practically be carried out without the waiver or alteration.

7.6.4 Whenever appropriate, the subjects shall be provided with additional pertinent information after participation.

7.6.5 Published or released astronaut data and other human experimental data derived from or associated with such approved research shall not be attributable to any individual.

7.7 NPR Shall Not Preempt Current Laws

The informed consent requirements in this NPR shall not preempt any applicable Federal, State, or local laws that require additional information to be disclosed in order for informed consent to be legally effective.

7.8 Physician Right to Practice Emergency Medicine

Nothing in this NPR is intended to limit the authority of a physician to provide emergency medical care to the extent that the physician is permitted to do so under applicable Federal, State, or local law.

| TOC | ChangeHistory | Preface | Chp1 | Chp2 | Chp3 | Chp4 | Chp5 | Chp6 | Chp7 | Chp8 | Chp9 | Chp10 | Chp11 | Chp12 | Chp13 | Chp14 | Chp15 | Chp16 | Chp17 | AppdxA | AppdxB | AppdxC | ALL |

| NODIS Library | Program Formulation(7000s) | Search |

DISTRIBUTION:
NODIS